REMARKS

Applicant respectfully requests reconsideration.

Claims 1, 2, 4-25, 42 and 86-98 were previously pending in this application. Claim 22 is cancelled without prejudice or disclaimer. Claims 1, 2, 21, 23, 24, 25, 42, 86 and 87 are amended. Applicant reserves the right to pursue the subject matter of any previously pending or originally filed claim in one or more continuing applications.

New claim 99 is added. No new matter has been added.

As a result, claims 1, 2, 4-21, 23-25, 42 and 86-99 are pending for examination.

Withdrawn Rejections

Applicant acknowledges the Examiner's withdrawal of rejection of

(a) claims 1, 2, 4-20, 42, 87, 90 and 91 under 35 U.S.C. § 112, second paragraph,

(b) claims 1, 2, 4-16, 18-24, 42 and 86-97 under 35 U.S.C. §102(b) as being anticipated by McKenney et al. (Infect. Immun. 66: 4711-4720, 1998),

(c) claims 1, 2, 4-25, 42 and 86-98 under 35 U.S.C. §103(a) over US patent 7252828 in view of Fattom et al. (Infect. Immun. 66:4588-4592, 1998),

(d) claims 17, 25 and 98 under 35 U.S.C. §103(a) over McKenney et al. (Infect. Immun. 66: 4711-4720, 1998) in view of Pier et al. (US 20020119166), and

(e) claims 1, 2, 4-25, 42 and 86-98 for obviousness type double patenting in view of US 7252828 in view of Fattom et al. (Infect. Immun. 66:4588-4592, 1998).

Rejection under 35 U.S.C. §112, first paragraph, new matter

Claims 1, 2, 4-25, 42 and 98 are rejected under 35 U.S.C. §112, first paragraph, for allegedly reciting new matter.

Claim 1 is rejected because the Examiner considers the recitation of "isolated beta-1,6-glucosamine polymers" to be new matter in view of the previous recitation of "isolated polysaccharide comprising a beta-1,6-glucosamine polymer". Applicant disagrees.

The claims as previously pending were directed to polysaccharides, which are themselves polymers, which comprised beta-1,6-glucosamine polymers. Such polysaccharides therefore could

have been entirely beta-1,6-glucosamine polymers or they could have comprised such polymers as well as other moieties. In either event, the polymer is still a polysaccharide as it comprises multiple glucosamine monomers. Accordingly, Applicant clearly contemplated and had possession of isolated beta-1,6-glucosamine polymers. The claims as previously pending and as originally filed provide support for claim 1 for reasons provided above. The specification provides an example of a glucosamine polymer on page 3 lines 16-21. The specification further states that "Accordingly, the polysaccharide may be a hetero-substituted polymer, wherein the R groups are a mixture of acetate substitutions (i.e., -NH-CO-CH_3) and unsubstituted amine (i.e., -NH_2) groups, provided that less than 50% of these groups are substituted with acetate." (See page 4 lines 21-25, emphasis added.)

Claim 2 is further rejected for the recitation that the polymers are conjugated to carrier compounds. Claim 2 has been amended to recite an isolated polymer conjugated to a carrier compound. Support for this amendment can be found at least in claim 2 as originally filed which recited " ... an isolated polysaccharide comprising a beta-1,6-glucosamine polymer ... conjugated to a carrier compound ...".

Claim 25 is further rejected for the recitation of a carrier compound that is polysaccharide that is not an N-acetyl beta-1,6-glucosamine polymer. The specification teaches that "The carrier compound may be a polysaccharide and that in some embodiments the carrier polysaccharide is not an N-acetyl beta 1-6 glucosamine. (See page 5 lines 15-19.) The specification further teaches that "Carrier compounds include ... polysaccharides, ... or other polymers ...". (See page 18 lines 10-11.) Accordingly, Applicants contemplated that the carrier compound could be a polysaccharide or a polymer. Applicant previously amended claim 25 to recite polymers in order to be consistent with such teaching (i.e., that the carrier could be a polymer).

A full reading and understanding of the specification evidences that the specification provides the requisite support for the claims as pending. Claims 1, 2, 4-25, 42 and 98 are fully supported by the specification, thereby evidencing that Applicant was in possession of such claims and that such claims do not contain new matter. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §112, first paragraph, written description

Claims 21, 86 and 97 are rejected under 35 U.S.C. §112, first paragraph, for allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention.

Without conceding the Examiner's position and rather in the interest of expediting prosecution, Applicant has amended claims 21 and 86 to recite that only one of X1, X2, X3, X4, X5, X6, Y1, Y2 or Y3 is the carrier compound or the linker joined to the carrier compound. This limitation can be found in claim 22 which was not rejected by the Examiner. Therefore the rejection should be overcome in view of this amendment.

However, for the record, Applicant traverses various statements made by the Examiner with respect to the written description rejection. First, the Examiner states that the "product of the rejected claims is required to serve as or intended to be used as a 'vaccine'." Applicant respectfully disagrees. The polysaccharide of the rejected claims may be used to induce active immunity in a subject, including to induce antibody production in a subject, but its use is not so limited. Claim 97, which depends from claim 86, recites that the polysaccharide is formulated as a vaccine. This clearly evidences that the scope of claim 86 is broader than simply a vaccine composition. Furthermore, the specification clearly states that the polysaccharide may be used as a screening reagent in order to identify peptides that bind to it. (See page 25 line 29 through to page 26 line 15 teaching that "The compositions of the invention are useful for many in vivo, and in vitro purposes. For example, the compositions of the invention are useful ... as an antigen to screen for biological agents such as monoclonal antibodies capable of preventing Staphylococcal infection, libraries of genes involved in making antibodies, or peptide mimetics ...".) The Examiner has apparently disregarded these uses and, in doing so, has failed to provide any basis for why derivatization would impact such non-vaccine uses.

Second, the Examiner relies on Wessells et al. Infect. Immun. 66:2186-2192, 1998 to support the argument that modification of the polysaccharide precludes its use as a vaccine. However, a full reading of Wessells et al. does not support this position. For example, in the Abstract, Wessells et al. clearly states that "Immunogenicity testing of a series of vaccines prepared with different degrees of polysaccharide-to-protein cross-linking demonstrated higher polysaccharide-specific antibody responses as the extent of cross-linking increased." (See page

2186, Abstract, lines 12-14.) This finding is summarized in Table 3 and on page 2189, first column, lines 3-8 which states that "The $\log_{10}$ polysaccharide-specific IgG level in immune sera was strongly correlated with the degree of sialic acid oxidation, i.e., extent of cross-linking, in the vaccines ($r = 0.98$). All four vaccines were protective (94 to 100% survival) in the maternal immunization-neonatal mouse challenge model of GBS infection (Table 3)." Although Wessells et al. further reports that opsonic activity varies depending on the extent of cross-linking (see, for example, FIG. 2), there is no evidence that opsonic activity is abrogated by cross-linking. To the contrary, each of the conjugates tested demonstrated opsonic activity, albeit to varying degrees and in dose-dependent manners, and Wessells et al. reported that the most opsonic conjugate was one characterized as moderately cross-linked and having 66% of sialic acids oxidized (as compared to conjugates having 18% or 35% of sialic acids oxidized. Accordingly, Wessells et al. does not stand for the proposition that highly cross-linked conjugates would not function as vaccines. The Examiner provides no other evidentiary basis for this argument.

Third, the Examiner further states "conception cannot be achieved until reduction to practice has occurred." Applicant respectfully traverses. Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." Hybritech Inc. v. Monoclonal Antibodies Inc. 802 F.2d 1367, 1376, 231 USPQ 81, 87 (Fed. Cir. 1986).

Applicant expressly reserves the right to pursue the subject matter of claims 21, 86 and 97 as pending prior to this amendment in one or more continuing applications.

Rejection under 35 U.S.C. §112, second paragraph

Claims 22-25, 42 and 86-97 are rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite.

Claim 22 is rejected for reciting "a carrier compound". Claim 22 has been cancelled.

Claims 22-24 are rejected for reciting that a carrier compound or linker is conjugated or joined to the structure. Claim 22 has been cancelled. Claims 23 and 24 have been amended to recite that only one of X1, X2, X3, X4, X5 or X6 (claim 23) or only one of Y1, Y2 or Y3 (claim 24) is the carrier compound or the linker.

Claim 42 is considered vague, according to the Examiner, because "it is unclear what this immune response is directed against". Claim 42 has been amended to recite that the response is against bacteria that make PNAG. Support for this amendment can be found in the specification at least on page 26 lines 16-17.

Claims 86 and 87 are rejected for reciting "a structure". Claims 86 and 87 have been amended to recite "the structure", as suggested by the Examiner.

The claims are definite. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C. §102

Claims 1, 2, 4-6, 8-25, 42 and 86-98 are rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 7252828 (Pier et al.). Applicant traverses.

According to the Examiner, Pier et al. teaches a product that is "not required to be acetate substituted and therefore have 0% acetate substitutions, i.e., less than 40%, less than 50%, or less than 35% acetate substitution." The Examiner has cited the passage at column 3, lines 4-19 in Pier et al. in support thereof. This passage however refers to an example of PS/A, defined at column 2 line 50 through to column 3 line 3, as having at least 50% of R groups that are NH-CO-CH_3. The passage at column 3 lines 4-19 does not change the level of acetylation of this PS/A example and rather it only introduces X and Y moieties that may be hydrogen, carrier compounds or linkers joined to carrier compounds. The Examiner further cites the structure disclosed in column 3 of Pier et al. for support. Although Applicant is unclear which of the two structures the Examiner is referring, both require that at least 50% of R groups be acetylated. No other passage cited by the Examiner supports a finding of a PS/A antigen that is less than 50% acetylated. Thus, the products disclosed in the cited passage are required to be at least 50% acetylated rather than non-acetylated as concluded by the Examiner.

The Examiner further states that Applicant has previously acknowledged that the PS/A antigen of Pier et al. "comprises acetate-unsubstituted and/or succinate-unsubstituted glucosamine residues, i.e., 0% acetate-substituted glucosamine residues." Applicant strongly disagrees. The Examiner has mischaracterized Applicant's previous comments relating to the PS/A of Pier et al. In

the response dated December 17, 2008, Applicant stated that "the polysaccharide of claim 1 may be composed of glucose, galactose, and/or glucosamine residues. The glucosamine residues may be acetate-substituted, succinate-substituted, and/or unsubstituted." That PS/A may be composed acetate-substituted, succinate-substituted, and/or unsubstituted glucosamine residues does not mean that PS/A is composed solely of unsubstituted glucosamine residues, as concluded by the Examiner.

Finally, the Examiner has herself previously admitted that (a) the PS/A antigen of claim 1 of the '828 patent has between 50-100% acetate substitutions and (b) "the '828 patent does not expressly state that less than 50%, 45%, or 40% of glucosamine amino groups ... are substituted with acetate." (See Office Action dated June 17, 2008, page 6 paragraph 21 lines 8-16, page 7 first full paragraph, and page 12 first and second full paragraphs.) Importantly, the Examiner previously relied on Fattom et al. (Infect. Immun. 66:4588-4592, 1998) for the teaching of reduced acetylation since such teaching is clearly absent from Pier et al. The Examiner is now taking a position that is inconsistent with her earlier position and is unsupported by the cited reference. This is improper. Applicant is entitled to and hereby requests a good faith effort by the Examiner to move prosecution forward.

For at least these reasons, Pier et al. does not anticipate the rejected claims. Reconsideration and withdrawal of the rejection is respectfully requested.

Double Patenting Rejection

Claims 1, 2, 4-6, 8-17, 19-25, 86-94 and 96-98 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 1 of US Patent No. 7252828. Claims 18, 42 and 95 are rejected under the judicially created doctrine of obviousness-type double patenting over claim 9 of US Patent No. 7252828 (Pier et al.).

As stated above, the Examiner has mischaracterized the PS/A antigen of claims 1 and 9 of Pier et al. Specifically, the Examiner has incorrectly concluded that such PS/A "is not required to have acetate substituted glucosamine residues ...". The Examiner has improperly read the passage on column 3 lines 4-19 of Pier et al. out of context. When read in proper context, this passage clearly refers to an example of PS/A having at least 50% of acetylated R groups. (See column 2 line 50 at least through to column 3 line 19.)

Furthermore, the Examiner has also mischaracterized Applicant's own statements respecting PS/A. In a response dated December 17, 2008, Applicant stated that "the polysaccharide of claim 1 may be composed of glucose, galactose, and/or glucosamine residues. The glucosamine residues may be acetate-substituted, succinate-substituted, and/or unsubstituted." That PS/A may be composed of acetate-substituted, succinate-substituted, and/or unsubstituted glucosamine residues does not mean that PS/A is composed solely of unsubstituted glucosamine residues, as concluded by the Examiner.

Finally, the Examiner has herself previously admitted that (a) the PS/A antigen of claim 1 of the '828 patent has between 50-100% acetate substitutions and (b) "the '828 patent does not expressly state that less than 50%, 45%, or 40% of glucosamine amino groups ... are substituted with acetate." (See Office Action dated June 17, 2008, page 6 paragraph 21 lines 8-16, page 7 first full paragraph, and page 12 first and second full paragraphs.) Importantly, the Examiner previously relied on Fattom et al. (Infect. Immun. 66:4588-4592, 1998) for the teaching of reduced acetylation since such teaching is clearly absent from Pier et al. The Examiner is now taking a position that is inconsistent with her earlier position and is unsupported by the cited reference. This is improper. Applicant is entitled to and hereby requests a good faith effort by the Examiner to move prosecution forward.

For at least the foregoing reasons, Pier et al. does not render obvious the rejected claims. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, the Director is hereby authorized to charge any deficiency or credit any overpayment in the fees filed, asserted to be filed or which should have been filed herewith to our Deposit Account No. 23/2825, under Docket No. B0801.70255US01.

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Respectfully submitted,

By _____

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